K073458

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Summary

APR - 4 2008

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Date of this summary: May 30, 2006

Name of the device: BTLock Implant System
Trade or Proprietary Name: BTLock Implant System
Common or Usual Name: BTLock Implant System
Classification Name: Endosseous Implant (21 CFR 872.3640)

The legally marketed devices to which we are claiming substancial equivalence, according 807.92(a)(3), are the following:

Reference#	Device Name	Manufacturer
K041661	NOBEL BIOCARE ENDOSSEOUS IMPLANTS	NOBEL BIOCARE UAS
K051461	3I OSSEOTITE DENTAL IMPLANTS	IMPLANT INNOVATIONS INC.

Description of the device

BTLock implant system is composed by a fixture and an abutment, joined together by a through screw. Main feature of BTLock implant system is an original and patented internal connection (US patent n° 6659700 B2 dated December 9th 2003). This connection has not compatibility with other system. All prosthetic components and accessories are exclusive for BTLock implant system.
BTLock implants are threaded, root-form dental implants, intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore chewing function to partially or fully edentulous patients.
BTLock implants are machined from titanium and available tapered. The implants may a) have a surface that consists of a titanium oxide layer, i. e. TiUnite implants (BT-Tite One and BT-Tite Standard Line); b) be coated with hydroxyapatite powder, i. e. HA Coated implants, (HA Coated Standard Line); or c) Acid-Etched (Acid-Etched Standard Line).
BTLock implant lines may differ also for the kind of thread (One or Standard), while keeping always the same kind of connection. All prosthetic components are indeed compatible with same-sized diameter of all lines.
BTLock implants may be placed in the oral cavity using either a single stage surgical procedure or a two stage surgical procedure. If a single stage procedure is used, the implants may be placed anywhere in the upper or lower jaw where good initial stability can be obtained.

Intended use

BTLock Implants are indicated for single or multiple tooth replacement, or for use in terminal or intermediate edentulous sites in the mandible and/or the maxilla, and for totally edentulous arches. The system is designed to be surgically inserted in the bone structure of the mouth in order to replace missing teeth.

As reported in BTLock surgical protocol, while selecting a candidate to implant treatment, some aspects should be carefully considered:

- Patient's expecations and motivations
- Patient's general health conditions
- Oral hygiene

General contraindications:
Low motivatiôn, bad oral hygiene, cronical or tumoral illness, exceeding use of addicting substances, atrophy of maxillary teeth, illness of neuropsychiatric system, bone growth in progress.

Proposed Labelling

BTLock products may feature basically two kinds of labelling, according the need for gamma-ray sterilisation:

1. Assembled Fixtures (fixture plus cover/surgical screw, assembling screws, implant carrier cap, no-touch delivery carrier), which require gamma-ray sterilisation and feature a double labelling (A + B). Each packed implant include also an information sheet, specific for BTLock fixtures.
2. Healing screws, which require gamma-ray sterilisation but feature only one labelling (A). It does not require an information sheet.
3. Other accessories (abutments and instrumentation) does not required gamma-ray sterilisation and feature only one labelling. They does not require information sheet.

BTLock conforms to 93/42/ECC UE Directive for Medical Devices.

1. Labelling for assembled fixtures:

Assembled fixtures feature a double labelling (LABEL A). See attachment I (Labelling).

Information reported are the following:

- Product Description
- Product Code
- Size (diameter, length). Diameter indicated also by colour code.
- Expiry Date
- Manufacturing Date
- Batch Number
- CE Mark
- Sterile Mark
- One-time Use Mark
- Mark to indicate to read information sheet
- Details of manufacturing company

All the same details are reported also on the label of the internal packaging (LABEL B). Label B is smaller than label A, because it must be used by the dentist in order to record the implant used on patient form. See attachment I (Labelling).

Each implant is packed with an information sheet in 4 different languages. See information sheet in attachement II (information sheet).

2. Labelling for healing screws.

Healing screw require gamma-ray sterilisation. They feature only one label, exactly as Label A previously described. See attachment I (Labelling).

3. Labelling for other accessories.

Labelling for other accessories, prosthetic included, is simplier than fixtures and healing screws' one, because gamma-ray sterilisation is not nedeed at all (LABEL C). See attachment I (Labelling).

Information reported are the following:

- Product Description
- Product Code
- Size (diameter, length)
- Manufacturing Date
- Batch Number
- CE Mark
- One-time Use Mark
- Details of manufacturing company

Description of devise design requirements

All details of products are included in their technical drawings. We include as attachment technical drawings for products class II (fixtures + healing screws). Anyway, all technical drawings are available for FDA review. Considering that the 'critical point' are fixtures and healing screw and that all the techincal drawings are more than 70, we prefer reducing the number of technical drawings to be attached. See attachment III (techincal drawings).

Identification of the risk analysis method

BTlock risk management is carried on according standard 14971 UNI CEI EN ISO.

BTLock products' risk are exactly the same of predicate devices, because materials used, treatments and general mechanical properties are substancially equivalent.
Anyway, BTLock has carried on both biocompatibility and mechanical testings anda multi-centered clinical study to proove the effectiveness of the devices before commercialisation.
Biocompatibility testings include:

- Citotoxicity – Eluation test* (attachment IV)
- Skin sensitization test* (attachment IV)
- Salmonella typhirium reverse mutation assay* (attachment IV)
- Intramuscular implantation test* (attachment IV)
- Intracutaneous reactivity test (attachment V)
- Pyrogenicity test (USP 151) (attachment VI)
- Sterility (ISO 11737-2) (attachment VII)
- Systemic toxicity test (attachment VIII)

* = Those testing were done in 2001 on implants with a different coating (plasma spray). As that surface is basically riskier than our current surface and the design was the same, we consider those testing valid also for current products. Also note that the name of BTLock was previously FIDELM sas until end of 2002.

Our quality system include a serie of internal and external checks over our products.

Internal checks are described in our quality system handbook and epsecially in our POS (standard operational procedures) documents. If needed we may provide a summary of those documents.
External checks are basically trhe followings:

- SEM analysis (attachment IX)
- Bioburden (attachment X)

Also it may be interesting to have a look at our Sterilisation contract specifications (attachment XI), valid for fixtures and healing screws.

Discussion of the device characteristics

We don't see relevant differences with respect to predicate devices. Anyway, BTLock carried on both mechanical testings (by Politecnico di Milano, Milan University) adn a multi-centered clinical study over its products.
Please see Mechanical testings (attachment XII) and Clinical Study (attachment XIII).

Materials used to produce BTLock System are described as follows:

1. **Fixtures (DZE)**

Composition of BTLock fixtures may change in accordance to the diameter. All BTLock fixtures (BTICV1, BTIVMA, BTIVHA, BTIVSM, etc...) are made of pure medical titanium, whose grade is reported in the following list:

Diameter	**3.30mm**	**3.75mm**	**4.50mm**	**5.50mm**	**6.50**
Titanium Grade	**IV**	**IV**	**II**	**II**	**II**

The composition of each grade of titanium used is reported in the following list:

- Titanium grade IV: (%)

C 0.041 Fe 0.15 O 0.32 N 0.099 H 0.0008 Ti: Bal

- Titanium grade II: (%)

C 0.0003 Fe 0.038 O 0.118 N 0.01 H 0.0019 Ti: Bal

See related titanium certificates.

Commercial product codes related to the previous composition:

BTIVA*, BTIVMA, BTIVPS*, BTIVHA, BTICV1, BTICHA*, BTICPS*

* = Not for Export

2. **Prosthetic Components (NHA)**

All BTLock prosthetic components, except from fixation screws and castable abutments, are made of titanium alloy (titanium grade V). The following is then the composition:

- Titanium grade V: (%)

Al 5.91 V 3.81 C 0.014 Fe 0.16 O 0.11 N 0.006 H 0.0019 Ti: Bal

Manufacturing codes related to the previous description:
BTIANL, BTIIPIM, BTITLC, BTIMTL, BTICTLS, BTIMP, BTIPMLS, BTIPMA, BTIPMCR, BTIPML, BTIPMLE, BTIPMLI, BTIPMLIE, BTIPMOC, BTIPMOR, BTIVG, BTIVT, BTIVFC, BTIVPS.

Fixation screws (except from BTIVPS) are instead made of stainless steel. Here the composition:

- Steel AISI 316 L

C 0.03 Si 0.60 Mn 1.43 Cr 18.00 Ni 10.00 Mo 2.00 P 0.04
S 0.03 N 0.07

Manufacturing codes related to the following description:

BTIVPC, BTIVPL.

Castable abutments are made of Plexiglas (polymethyl methacrylate).
Product codes related to the previous description are:
BTIMCL, L BTIMCL, BTICSF, BTICTX, BTICMP.

3. Instrumentation (NDP)

Instrumentation may be made either of stainless stell or titanium grade V.
This is the composition:

- Steel AISI 316 L

C 0.03 Si 0.60 Mn 1.43 Cr 18.00 Ni 10.00 Mo 2.00 P 0.04
S 0.03 N 0.07

- Titanium grade V: (%)

Al 5.91 V 3.81 C 0.014 Fe 0.16 O 0.11 N 0.006 H 0.0019 Ti: Bal

Manufacturing codes related to the previous description are:
BTIKITC, BTICVQ, BTICVL, BTIMS, BTISL, BTICCBM, BTICCD, BTICCQ, BTICR, BTICDIN, BTIIPR, BTIIPA, BTIBOX, BTIPRF, BTIFP, BTICV, BTIIPIM, BTICVM, BTICVLM, BTICQM, BTITW, BTIFC, BTIFCA, BTISP, BTIFSV, BTIOSS, BTIES.

For FDA review, we attach titanium certificates (attachment XIV).

About surfaces of fixtures, the fixtures which will be imported to US features only two kind of treatments:

1. BT-Tite (the same concept of SLA of Straumann or Osseotite of 3I). We believe there is not need to proove the effectiveness and the safety of this kind of surface. Anyway we did many biocompatibility and mechanical testings (see attachments I-XIII)
2. HA Coating (attachment XVIII)

More relevant documents

In order to complete the documentation, we consider very important to attach other documents like:

- CE certificates (attachment XV)
- Change of corporate name (from Fidelm Sas to BTLock Srl) (attachment XVI)
- Free trade certificate (attachment XVII)
- Ha Coating (external treatment) (attachment XVIII)**
- ISO 9002 + 13488 by DNV (attachment XIX)
- Patent for BTLock connection (attachment XX)

** = please note that the coating on our fixtures is K630. The taber testings are carried over a similar coating called Osprovit. Please read the letter from our supplier explaining the mechanical equivalence.

We believe there is not specific reason to explain

We are available for any doubt or query.

Diego La Rosa
Export Manager
BTLock srl

Alte Ceccato (VI – Italy), May 30th 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Ms. Ester Battilana
BTLock S.R.L
Via Madonnetta 97/C
36075 Montecchio Maggiore
Vicenza, ITALY

Re: K073458
Trade/Device Name: BT Lock Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 19, 2008
Received: March 19, 2008

Dear Ms. Battilana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

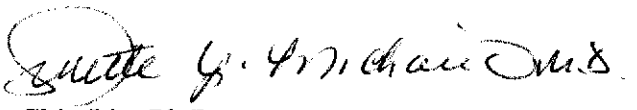
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073458

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Indications for Use

510(k) Number: **K073458**

Device Name: **BTLock Implant System**: BT Tite CVz (BT-Tite One or CV1; BT-Tite CV2 or CV2), BT-Tite Standard or VSMz (VSM, VSM1, etc.)

Indications for Use

BT-Tite Standard (or VSM) It is intended to be used in maxilla or mandible, and for every kind of reconstruction, preferably not immediately loaded. It is intended to be used in a single stage or two stage surgical procedure.

BT-Tite One (or CV1) It is intended to be used in maxilla or mandible, for extraction sites and where the implant would be immediately loaded. It is intended to be used in a single stage or two stage surgical procedure.

BT-Tite CV2 (or CV2) It is intended to be used in maxilla or mandible. It is indicated in any situation for extraction sites, where the implant would be immediately loaded and where the bone crest is stable. In case of post-extraction sites, it has to be inserted some millimetres under the bone. It is intended to be used in a single stage or two stage surgical procedure.

Susan Runner 4/4/08

(Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K073458

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

Concurrence of CDRH, Office of Device Evaluation (ODE)